Case No.:UCIVN-003C
Certificate of Mailing:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wong, et al.	Art Unit: 1615
Serial No.: 10/733,835	Examiner: Azpuru, Carlos A.
Filed: February 5, 2004``	
For: Methods for Preparing and Using Implantable Substance Delivery Devices	

DECLARATION PURSUANT TO 37 C.F.R. § 1.131

I, Corrinne Gail Wong, do hereby declare as follows:

1. I was previously employed by the Regents of the University of California and held an appointment as Adjunct Professor in the Department of Ophthalmology, School of Medicine, University of California Irvine (hereinafter referred to as the "University"). I have read and am familiar with the content of United States Patent Application Serial No. 10/733,835 (hereinafter referred to as the "'835 Patent Application").

2. It is my understanding that claim 35 of the '835 Patent Application reads as follows:

> 35. A method for preparing an implantable device for a sustained delivery of a substance within a body of a human or an animal subject, said method comprising the steps of:

(A) dissolving a biocompatible polymer in a suitable solvent solution to produce a polymer-solvent solution;

(B) adding said substance to said polymer-solvent solution to produce a polymer-solvent solution-substance admixture;

(C) drying said polymer-solvent solution-substance admixture to form a substantially dry mass;

(D) adding a liquid to said mass to cause said mass to soften and;

(E) manipulating said softened mass to a desired shape.

3. The method recited in claim 35 was conceived of by me and actually reduced to practice prior to June of 2000. Substance delivery implants made according to this method were subsequently used in animal studies performed at the University.

4. At least as early as 1998 I had been conducting animal studies where certain test substances were administered by intravitreal injection into the eyes of rabbits. In 1998 a decision was made to modify the study protocol to allow for intravitreal implantation of substance delivery implants containing the test substances, as well as intravitreal injection of the test substances. Also as of late 1998 or early 1999 I had begun to work on methods for preparing substance delivery implants for use in such experiments.

5. Appended hereto as Exhibit A is a true and exact copy of a protocol modification request that was prepared and signed by me in January of 1999 seeking modification of the existing study protocol to include surgical implantation of polymeric implants for sustained intravitreal delivery of growth factors VEGF and basic-FGF.

6. Appended hereto as Exhibit B is a true and exact copy of a confidential e-mail that was sent by me to other University employees on June 3, 1999 describing a method that, as of that date, had been conceived of by me and actually performed in the laboratory. This method results in preparation of implantable polymer pellets that contain growth factors VEGF and basic-FGF. Implants prepared according to this method were in fact used in subsequent animal studies conducted at the University after approval of the protocol modification requested in the document appended hereto as

Exhibit A.

I declare that all of the statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that such statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application or and patent issuing therefrom.

April 14, 2006 Corinne Gail Wong
Date Corinne Gail Wong